5. 510(K) SUMMARY

Endologix AFX Introducer System
510(k) Summary – K TBD
January 23, 2012

1. **Company:** Endologix, Inc.
11 Studebaker
Irvine, CA 92618

   Contact: Janet M. Fauls
VP, Regulatory and Clinical Affairs
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2. **Proprietary Trade Name:** Endologix AFX Introducer System, Model S17-45

3. **Classification Name:** Catheter, Introducer (21 CFR 870.1340)

4. **Product Code:** DYB

5. **Product Description:**

The Endologix AFX Introducer System, Model S17-45 consists of an Introducer Sheath (45cm working length), Dilator, and a peel-away wire straightener.

The AFX Introducer System is a single-use sterile device that is compatible with a standard 0.035" guidewire.

- *Introducer Sheath:* The Introducer Sheath provides a conduit for introducing other interventional devices, including guidewires and interventional catheters, into the vasculature. The main components of this assembly are a hydrophilically-coated polytetrafluoroethylene (PTFE) lined 55D Pebax introducer sheath, acrylobutylstyrene (ABS) hemostasis valve housing with silicone valve and gasket assembly, 3-way stopcock/valve, and sideport diethylhexyl phthalate (DEHP)-free polyvinylchloride (PVC) tubing. The Pebax introducer sheath also includes an embedded stainless steel braid for increased strength and kink resistance, and embedded Vectran® strands for increased longitudinal strength. The distal tip of the introducer sheath includes an embedded radiopaque marker composed of 90% Platinum/10% Iridium. The only change to the Introducer Sheath from that cleared under K111747 is replacement of the butyl rubber valve with a silicone valve and modification of the hemostasis valve housing to accommodate the silicone valve.

- *Dilator:* The dilator for this system is used to provide support and stability to the Introducer Sheath during deployment into the vasculature. The dilator is designed specifically for the Endologix AFX Introducer System and can accommodate a 0.035" guidewire through the

central lumen. The dilator is composed of 63D Pebax with 30% Barium Sulfate ($BaSO_4$) for radiopacity and a hydrophilic coating on the outer surface. The dilator is designed in diameter and length to be placed within the AFX Introducer Sheath component. The dilator has a tapered, atraumatic distal tip. The proximal end of the dilator includes a luer port. The dilator provides stiffness to the assembly so that the introducer sheath can be placed within the vasculature during standard vascular access. There are no changes to the dilator from that cleared under K111747.

- *Peel-away Wire Straightener:* A newly added peel-away wire straightener has been added to the AFX Introducer System as a convenience option for our customers. The peel-away wire straightener is useful in straightening guidewires prior to feeding into the introducer sheath. This 8 cm length wire straightener is identical in materials (55D Pebax), lumen and outer diameter, construction, and processing as the wire straightener currently packaged with the AFX Endovascular AAA bifurcated delivery system (approved under P040002/S031).

6. Indications

The Endologix AFX Introducer System, Model S17-45 is intended for use to facilitate the introduction of guidewires, catheters and other medical devices into the vasculature and minimize blood loss associated with such introduction.

7. Substantial Equivalence

Documentation provided includes a detailed comparison which demonstrates that the proposed AFX Introducer System, Model S17-45 is substantially equivalent to the current Endologix AFX Introducer System, Model S17-45 cleared under K111747. The descriptive characteristics of the proposed device are sufficient to ensure equivalence to the predicate device: In addition, the evaluations listed in Table 5-1 have been performed on the modified AFX Introducer System to support the determination of substantially equivalence to the 510(k) cleared AFX Introducer System:

Table 5-1: List of Evaluations Performed to Establish Equivalence to Predicate Device

Evaluation	Applicable test standard(s)
Functional/Mechanical Qualification	BS EN ISO 10555-1:2009
EO Gas Sterilization Validation	ANSI/AAMI/ISO 11135-1: 2007 AAMI TIR 28: 2009
Biocompatibility Testing	ISO 10993-1: 2009

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

FEB - 9 2012

Endologix, Inc.
c/o Janet M. Fauls
VP, Regulatory and Clinical Affairs
11 Studebaker
Irvine, CA 92618

Re: K120212
Trade/Device Name: AFX Introducer System
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II (two)
Product Code: DYB
Dated: January 23, 2012
Received: January 24, 2012

Dear Ms. Fauls:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: TBD K120212

Device Name: Endologix AFX Introducer System

Device Model: Model S17-45

Indications for Use: The Endologix AFX Introducer System is intended for use to facilitate the introduction of guidewires, catheters, and other medical devices into the vasculature and minimize blood loss associated with such introduction.

Prescription Use ___x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M-A. Villeneuve

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K120212